

# Impaction grafting of the acetabulum with ceramic bone graft substitute

## High survivorship in 43 patients with a mean follow-up period of 4 years

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**Background and purpose** Loss of bone stock remains a challenge in revision hip surgery. Grafting with allograft is well established, but there are problems with availability, cost, infection, antigenicity, reproducibility, and stability of the created construct. BoneSave is a biphasic porous ceramic consisting of sintered 80% tricalcium phosphate and 20% hydroxyapatite. In vitro and in vivo studies, including its use mixed with allograft, have shown good results in impaction grafting. This is the first reported series of its use alone in impaction grafting of the acetabulum.

**Methods** We conducted a retrospective review of a cohort of 43 consecutive patients undergoing impaction grafting of contained acetabular defects by multiple surgeons at a single centre. All patients received uncemented acetabular components. They were followed up radiographically, together with self-reported satisfaction scale (SAPS), Oxford hip score (OHS), and Short-Form 12 (SF12) health survey. Kaplan-Meier survivorship analysis was performed with revision of the acetabular component, revision of any part of the construct, and reoperation as endpoints.

**Results** The fate of all cases was known. Mean follow-up was 4 years. 5 patients died during follow-up, with their constructs in situ. The survivorship of the acetabular component was 98% (95% CI: 85–100) at 7 years. 1 acetabular component was revised for infection and there was 1 radiographic acetabular failure. The median OHS was 36 (6–48), the median SF12 PCS was 36 (14–57), the median SAPS was 75 (0–100), and the median SF12 MCS was 50 (23–64). The graft material had incorporated in all 3 zones of the acetabulum in 33 out of 37 cases with complete radiographic follow-up.

**Interpretation** Medium-term results show that BoneSave alone is a reliable material for impaction grafting of contained defects in the acetabulum at revision surgery.

Impaction grafting to restore bone stock and create a stable construct was made popular by the Exeter and Nijmegen groups (Gie et al. 1993, Slooff et al. 1996). Reported problems with allograft such as infection (Simonds et al. 1992), antigenicity (Friedlaender et al. 1984), lack of availability (Galea et al. 1998), and cost (Tomford et al. 1981) have led to the search for bone graft substitutes. Femoral head allograft has been shown to be more expensive than commercially available bone substitutes (per gram) in some countries (Leung et al. 2010).

Hydroxyapatite and tricalcium phosphates osseointegrate (Itokazu et al. 1996, Ransford et al. 1998) but their ability to maintain structural integrity under load has been questioned (Hanft et al. 1995). In conjunction with Stryker (Newbury, UK), our group has developed a biphasic ceramic bone graft substitute, called BoneSave, specifically for use in impaction grafting in revision hip surgery. Mechanical engineering studies have demonstrated that BoneSave combined with allograft is more stable and more reproducible than allograft alone in an impaction grafting model (Blom et al. 2002). Furthermore, stability and reproducibility are directly proportional to the ratio of BoneSave to allograft. Studies in sheep have shown the clinical effectiveness of BoneSave when used as a bone graft extender (Blom et al. 2005). We have already reported good results using BoneSave combined with allograft in acetabular impaction grafting in revision hip surgery in patients (Blom et al. 2009, Whitehouse et al. 2013). Until now, there have been no reports of BoneSave being used without allograft in impaction grafting. Here we report the medium-term follow-up of a cohort of patients undergoing grafting of acetabular defects with BoneSave only, a biphasic tricalcium phosphate/hydroxyapatite porous ceramic bone graft substitute that is sintered at high temperature to allow the necessary mechanical properties to be used in impaction grafting.

## Patients and methods

43 patients (26 female) underwent revision hip arthroplasty with grafting of BoneSave bone substitute alone between July 2004 and October 2010. Before July 2004, BoneSave had been used in our unit for acetabular grafting in combination with femoral head allograft. This was a series of patients presenting with contained acetabular defects that required grafting. Medial defects that were supplemented with a mesh in the floor were included but other uncontained defects that required the use of a rim mesh were excluded.

In 35 cases, the femoral component was also revised at the time of index surgery. In 25 cases, a cemented femoral component was inserted (15 C-stem AMTs (DePuy International, Leeds, UK); 6 CPTs (Zimmer Inc., Warsaw, IN); 4 Exeter stems (Stryker, Newbury, UK), and in 10 cases an uncemented component (9 KAR stems and 1 S-ROM (DePuy)). All acetabular defects were grade B according to the classification of Parry et al. (2010). The median percentage of host bone contact with the implanted component was 70% (IQR 55–80, range 0–90). In all cases, the acetabular component inserted was uncemented (28 Pinnacle and 4 Duraloc (DePuy); 3 Trident, 2 ABG, and 3 Omnifit (Stryker); 2 Procotyle (Wright Medical Technology Inc., Arlington, TN) and 1 Trilogy (Zimmer)). In 38 of the cases, supplementary screw fixation was used for the acetabular component following assessment of stability by the treating surgeon. A median of 3 (0–6) screws were used. In 18 cases, a metal-on-polyethylene bearing was used, in 18 a metal-on-metal bearing was used, and in 7 a ceramic-on-ceramic bearing was used.

Median age at surgery was 73 (28–92) years. 5 patients died during the follow-up period, at a median age of 84 (80–94) years. The period of follow-up was normally distributed. For patients who remained alive at final follow-up, the mean time was 51 months (SD 19). When patients who had died were included, the mean follow-up until final follow-up or death was 49 months (SD 20). There was a total of 176 person years of observation. Of the 38 patients who remained alive at final follow-up, 36 of them returned completed questionnaires (see below).

This study was conducted as a service evaluation (National Research Ethics Service 2007). A questionnaire consisting of a validated self-administered patient satisfaction scale (SAPS) (Mahomed et al. 2011), an Oxford hip score (OHS) (Dawson et al. 1996), and a Short-Form 12 (SF12) health survey (Ware et al. 1996) was sent to each patient, with a cover letter, on 2 separate occasions. An additional question was asked: whether the patient would undergo the same surgery again in light of their preoperative and postoperative symptoms and function. If patients did not respond, the hospital records system, picture archiving system (PACS), and the primary care records were used to determine whether they had undergone further surgery.

Radiographic analysis was carried out by MRW and AWB. Radiolucencies around the acetabular component on the latest

follow-up radiograph were assessed according to the method of DeLee and Charnley (1976). The presence or absence of graft incorporation in each of these zones was recorded according to the system described by the Oswestry group (Aulakh et al. 2009). Components were considered to have migrated if they had moved by 3 mm or more from the inter-tear drop line or trans-ischial line where this was obscured (Ritter et al. 1999). The grade of heterotopic ossification, according to the system of Brooker et al. (1973), and the presence of BoneSave in the soft tissues were recorded.

## Statistics

The distribution of data was checked for normality using the Kolmogorov-Smirnov test. Where the data were normally distributed, central tendency is given as mean with SD and parametric tests were used (2-tailed unpaired Student's *t*-test). Where the data were not normally distributed, central tendency is given as median with range; and in such cases non-parametric tests were used. Correlation was calculated using a Spearman rank test. Survivorship was analyzed with the Kaplan-Meier method, with 95% confidence intervals (CIs). The data were analyzed with revision of the acetabular component, revision of any part of the construct (acetabular component, bearing, or stem), and reoperation for any reason as endpoints.

## Results

The outcome scores were not normally distributed. The median SAPS was 75 (0–100). The median OHS was 36 (6–48). The median SF12 PCS was 36 (14–57) and the median SF12 MCS was 50 (23–64). 30 of the patients said they would have the operation again, 3 were unsure, and 3 said they would not undergo the operation again. There was no correlation between whether the patients would have the operation performed again and their OHS at final follow-up (–0.43).

Radiographic follow-up was available in 37 cases. 1 case had migrated and was considered a radiographic failure, but the patient was not fit to undergo further revision surgery. No osteolysis or accelerated polyethylene wear was observed. Graft incorporation had occurred in all 3 zones in 33 cases. In 2 cases, graft incorporation had not occurred in any zone and in 2 cases graft incorporation had not occurred in zone 2, where the graft was not loaded due to rim fixation of the acetabular component. According to the graft incorporation grading system of Aulakh et al. (2009), the median graft incorporation score was 3—indicating consolidation of the graft material (IQR 2–3, range 0–3) (Figures 1 and 2).

Brooker grade 0 was recorded in 21 cases, grade 1 in 12 cases, grade 2 in 2 cases, and grade 3 in 2 cases. In 4 cases, the Brooker grade was worse than preoperatively and in 2 cases the grade had decreased. Graft was visible in the soft tissues in 2 cases: 1 was Brooker grade 0 and 1 was grade 1, and

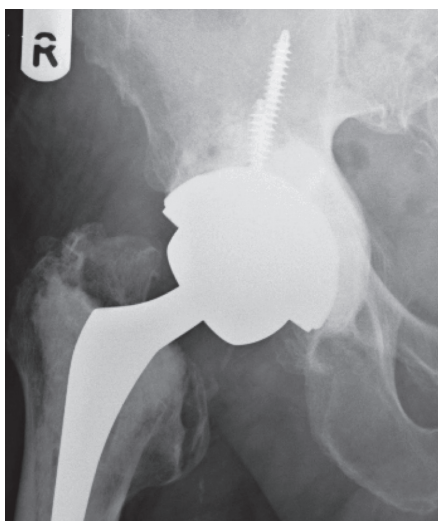


Figure 1. Radiograph of an illustrative case 1 year post operation.

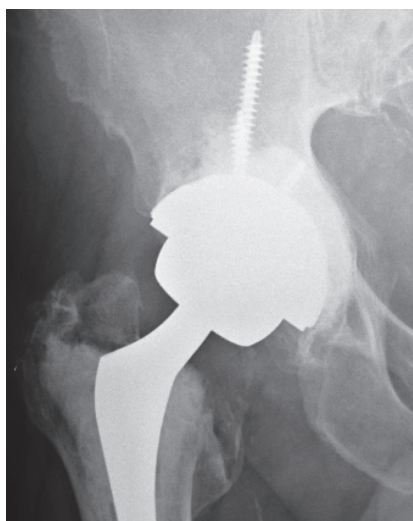


Figure 2. Radiograph of an illustrative case 4 years post operation.

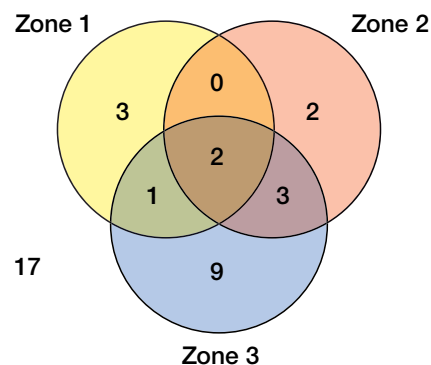


Figure 3. Distribution of radiolucencies by acetabular zone.

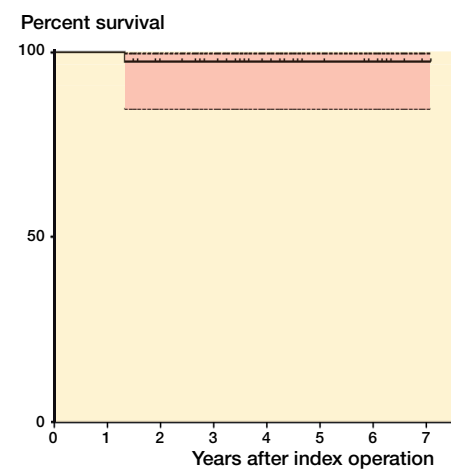


Figure 4. Kaplan–Meier analysis with 95% confidence intervals and number at risk with revision of the acetabular component as the endpoint.

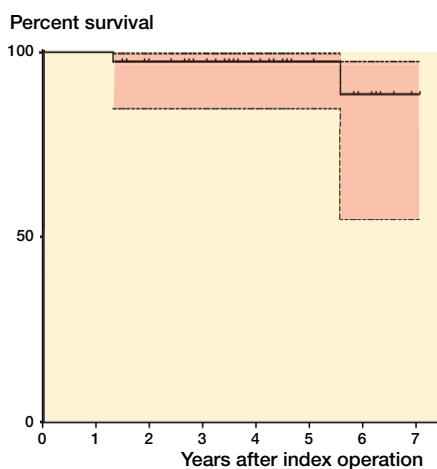


Figure 5. Kaplan–Meier analysis with 95% confidence intervals and number at risk with revision of any part of the construct as the endpoint.

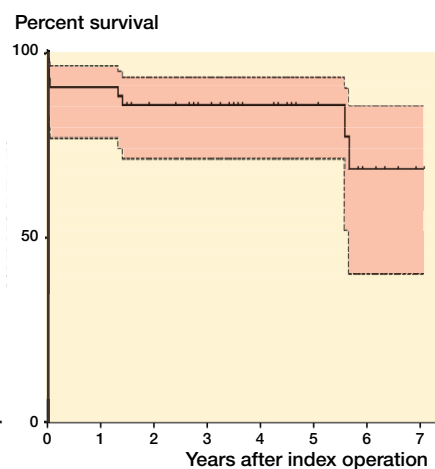


Figure 6. Kaplan–Meier analysis with 95% confidence intervals and number at risk with reoperation for any cause as the endpoint.

had been preoperatively. Of the 37 cases with radiographic follow-up, no radiolucency was observed in 17 cases (Figure 3). 1 of the 2 cases with radiolucency in all 3 zones was the radiographic failure already described; the other case had an OHS of 29.

1 acetabular component was revised for infection during the follow-up period (16 months after the index operation). 1 patient required revision of the femoral stem only for aseptic loosening (5.5 years). 6 patients required reoperations that did not involve revision of any part of the construct. 2 radical debridements were performed for infection (at 1 week and 3 weeks), 2 femurs required supplementary strut grafting of the femur (at 2 weeks and 5.5 years), 1 patient required closed

reduction for dislocation following a fall (at 1 week), and 1 patient underwent an examination under anesthetic to assess subluxation (at 1.5 years); the hip was found to be stable.

The survivorship of the acetabular component with grafting was 98% (CI: 85–100) at 85 months (Figures 4–6).

### Discussion

The results presented here are short- to medium-term, and must therefore be interpreted with caution. The heterogeneous case mix makes generalization of the results to patients undergoing revision hip replacement complex, but this is a reflection

of the patient population that presents for such procedures, as has been observed in other reports. In the medium to long term, good results have been reported for impaction grafting of allograft in the acetabulum in conjunction with the use of cemented components in primary hip replacement (Somford et al. 2008), primary and revision surgery (Schreurs et al. 2004, Busch et al. 2011), and revision with supplementation by use of autologous marrow and uncemented components (Deakin and Bannister 2007), but there may be a limit to the size of the defect that can be grafted (van Haaren et al. 2007).

We have previously reported our experience of the use of BoneSave in a 1:1 combination with allograft (Blom et al. 2009, Whitehouse et al. 2013), at a mean follow-up of 24 months and 7 years. There were no revisions or migration, with high patient satisfaction at the first follow-up. There were 2 revisions at the later follow-up, 1 for aseptic loosening and 1 for infection. Fujishiro et al. (2008) reported a series of 15 patients grafted with a 1:1 mix of allograft and a graft substitute with a much higher proportion of hydroxyapatite than used in BoneSave; 2 failures were reported, 1 at 16 months and 1 at 33 months. McNamara et al. (2010) did not report any revisions, but improved function and graft incorporation in 60% of hips grafted with a 1:1 mix of allograft and pure hydroxyapatite in a series of 48 patients with a mean follow-up period of 5 years. Migration was observed in 2 acetabular components. Kawanabe et al. (1998) used an apatite-wollastonite glass ceramic in combination with autograft or allograft in a series of 13 patients. Migration was seen in 1 out of 11 acetabular revisions and 1 out of 4 femoral revisions. The findings of Englbrecht et al. (2000) were similar in a series of 45 graftings with a mix of allograft and a granulate glass ionomer cement. Loosening was observed in 10 patients at a mean time of 30 months after revision in a series of 45 patients followed for a mean of 42 months.

A number of authors have reported the results of the use of bone graft substitutes on their own, rather than in combination with allograft or autograft. Oonishi et al. (1997) used hydroxyapatite granules to graft massive acetabular bone deficiencies in 40 patients undergoing revision. 3 patients had loosening and migration, with the remaining 37 showing good outcomes and bonding of the hydroxyapatite to bone. Schwartz and Bordei (2005) reported the use of biphasic phosphor-calcium ceramics for void filling (granules) and reconstruction of segmental defects (preformed shapes). At a mean of 5.5 years of follow-up, integration of ceramic with host bone was observed in all 32 hips. Femoral component subsidence of between 5 and 14 mm was observed in 8 cases. At 1-year follow-up, Egawa et al. (2009) found substantial new mineralization in 10 patients with symptomatic osteolysis who were treated with calcium sulfate bone graft substitute.

The OHS achieved by our patients was similar to those in published large series when adjustment was made for the different scoring method for the OHS used (Field et al. 2005). The proportion of patients who stated that they would undergo

the operation again is satisfying, and reflects the SAPS achieved. It is surprising to note that there was a negative correlation between OHS and whether a patient would undergo the operation again, but this is probably a reflection of individual patient variation and of the relatively small sample size.

There was 1 case of revision of part of the construct—for infection—in this series, which is consistent with our previously reported experience (Blom et al. 2003). When soft tissue debridements for infection were taken into account, the incidence in this series was higher than in our previous experience. The use of bone graft substitute alone does not eliminate the risk of infection in this high-risk group of patients, which is not surprising. The rates of infection in our series are similar to those reported by authors for similar-sized series (Englbrecht et al. 2000, McNamara et al. 2010).

Given the small numbers, formal testing of correlation was not determined to be useful. It is interesting to note that in the 2 cases with graft material visible in the soft tissues, the Brooker grade had not changed from before revision. Given that BoneSave is capable of incorporation and is osteoconductive but not osteogenic, and does not contain growth factors capable of osteoinduction other than those present in the host tissue, this finding fits with our understanding of the properties of bone graft materials.

There was a high incidence of graft incorporation in this series (33 of 37 cases with complete radiographic follow-up). Failure of graft incorporation in all 3 zones was not necessarily associated with clinical failure, with 1 case being determined to have failed but the other being clinically successful. The need to create a stable construct with loading of the grafted material is emphasized by the lack of incorporation of the graft in the 2 cases where rim fit had been achieved with the acetabular component. The incidence of graft incorporation was better than in other reported series (McNamara et al. 2010) and similar to the best reported results (Oonishi et al. 1997). The incidence of radiolucencies around the acetabular components in our series remains a cause for concern that we will continue to monitor with further follow-up. Although it is reassuring that implant migration has not occurred in these implants at medium-term follow-up—whereas in series where catastrophic failure has been reported with impaction grafting, this has occurred within a year of surgery (Eldridge et al. 1997, Charalambides et al. 2005)—it is possible that these radiolucencies could represent an interface that is not sealed, and therefore be susceptible to ingress of wear debris (Schmalzried et al. 1992) or be predictive of future migration (Ritter et al. 1999).

Limitations of our study include the lack of comparator groups without grafting and with the use of graft substitute mixed with autograft or allograft. We hope that surgeons will find our data useful to inform practice in the choice of graft material and add to the body of available evidence. The lack of standardized components and the range of follow-up is a reflection of the patients that present for revision surgery with

bone loss, and the variety of surgical techniques required to address this. Acetabular defects were classified according to the system of Parry et al. (2010); we find this system useful, as it helps to guide our treatment strategy. We have not attempted to classify the defects in this series using other recognized classification systems. The lack of correlation with intraoperative findings (Gozzard et al. 2003) limits the usefulness of such classification in a study of this nature. A high proportion of our patients received metal-on-metal bearing surfaces, and this may bias towards worse outcomes (Smith et al. 2012).

In summary, we have found that BoneSave, a biphasic tricalcium phosphate/hydroxyapatite porous ceramic bone graft substitute, when used without augmentation with autograft, allograft, or autologous marrow, to be reliable for grafting of contained defects of the acetabulum. It is associated with a low rate of failure and complications and it osseointegrates when suitably loaded by the construct.

MRW: data collection, radiographic analysis, and statistical analysis. PJD: data collection and statistical analysis. JCJW: surgery. AWB: data collection, radiographic analysis, and surgery. All the authors were involved in the study design and in conducting the study, and in manuscript preparation.

No competing interests declared.

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